THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
EASTERN DIVISION

LISA HARRIS and ORAL DUANE HARRIS, JR., **Plaintiffs,** **v.** **ELUTIA INC. f/k/a AZIYO BIOLOGICS, INC., MEDTRONIC SOFAMOR DANEK USA, INC., SPINALGRAFT TECHNOLOGIES, LLC, DCI DONOR SERVICES, INC., and NEW MEXICO DONOR SERVICES,** **Defendants.**	**CIVIL ACTION NO. 2:24-cv-8** **DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiffs, Lisa Harris and Oral Duane Harris, Jr., husband and wife, by and through their attorneys, and for their complaint against Defendants, Elutia Inc. f/k/a Aziyo Biologics, Inc. (hereinafter Elutia Inc. is referenced as "Aziyo"), Medtronic Sofamor Danek USA, Inc., Spinalgraft Technologies, LLC (hereinafter Medtronic Sofamor Danek USA, Inc. and Spinalgraft Technologies, LLC are referenced together as "Medtronic/Spinalgraft"), DCI Donor Services, Inc., and New Mexico Donor Services (hereinafter DCI Donor Services, Inc. and New Mexico Donor Services are referenced together as "Donor Services") allege as follows:

I. INTRODUCTION

1. This action seeks to recover damages for the personal injuries suffered by Plaintiff Lisa Harris as the direct and proximate result of the wrongful conduct of Defendants in connection with the research, testing, design, development, manufacture, tissue recovery, production, inspection, labeling, advertisement, marketing, promotion, sale, and distribution of a product known as FiberCel Fiber Viable Bone Matrix ("FiberCel") and the human tissue used to make FiberCel. Defendants' negligence resulted in personal injury suffered by the Plaintiff, Lisa Harris, after the FiberCel product was used in an implant procedure. Her spouse, Oral Duane Harris, Jr., alleges a claim for loss of consortium.

II. PARTIES

2. Plaintiffs Lisa Harris ("Plaintiff") and Oral Duane Harris, Jr., have been and are residents of the State of North Carolina, residing in Washington, North Carolina (Beaufort County).

3. Defendant Elutia Inc. f/k/a Aziyo Biologics, Inc., is a Delaware corporation, whose registered agent for service of process is Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808. Aziyo's principal place of business is located at 12510 Prosperity Drive, Suite 370, Silver Spring, Maryland 20904. Aziyo does business throughout the United States, including conducting regular business in North Carolina.

4. Aziyo sells a variety of medical products, including implantable electronic devices, orthopedic and spinal repair products, and soft tissue reconstruction products.

5. Upon information and belief, Aziyo developed, manufactured, marketed, promoted, distributed, and supplied the FiberCel product which was implanted into Plaintiff and caused her personal injury.

6. Defendant Medtronic Sofamor Danek USA, Inc. is a Tennessee corporation with a principal office address of 2600 Sofamor Danek Drive, Memphis TN 38132-1719, and with a registered agent listed as Corporation Service Company, 2908 Poston Ave, Nashville, TN 37203-1312. Medtronic Sofamor Danek USA, Inc. does business throughout the United States, including conducting regular business in North Carolina.

7. Defendant Spinalgraft Technologies, LLC is a Tennessee limited liability company with a principal office address at 4340 Swinnea Road, Memphis TN 38118-6603, and a registered agent listed as Corporation Service Company, 2908 Poston Ave, Nashville, TN 37203-1312. Spinalgraft Technologies, LLC does business throughout the United States, including conducting regular business in North Carolina.

8. Defendant Spinalgraft Technologies, LLC is affiliated with Defendant Medtronic Sofamor Danek USA, Inc.

9. Medtronic/Spinalgraft develop therapeutic and diagnostic medical products and are, along with their affiliates, among the world's largest medical technology, services, and solutions companies. Upon information and belief, Medtronic/Spinalgraft were directly and pertinently involved in the development, marketing, sale, and distribution of the FiberCel product herein and the Medtronic and Spinalgraft Defendants are jointly and severally liable for all causes of action herein.

10. Upon information and belief, during the pertinent times, Medtronic/Spinalgraft were designated as the exclusive U.S. distributor of the FiberCel product manufactured by Defendant Aziyo.

11. At all times relevant, Medtronic/Spinalgraft developed, distributed, supplied, and sold the FiberCel product which was implanted into Plaintiff, and which is the subject of this complaint.

12. Defendant DCI Donor Services, Inc. is incorporated in Tennessee, having its principal place of business at 566 Mainstream Drive, Suite 300, Nashville, TN 37228-1234, with a registered agent for service located at Corporation Service Company, 2908 Poston Ave, Nashville, TN 37203-1312. DCI Donor Services, Inc. is the parent company of New Mexico Donor Services. DCI Donor Services, Inc. does business throughout the United States, including conducting regular business in North Carolina.

13. Defendant New Mexico Donor Services is incorporated in New Mexico, having its principal place of business at 1609 University Boulevard NE, Albuquerque, NM 87102, with a registered agent for service located at Corporation Service Company, MC-CSC1726 E. Michigan Drive, Ste. 101, Hobbes, NM 88240. New Mexico Donor Services does business throughout the United States, including conducting regular business in North Carolina.

14. DCI Donor Services, Inc. and New Mexico Donor Services (collectively, "Donor Services") are engaged in the business of, inter alia, locating, properly identifying and qualifying, and recovering parts of human cadavers that should at all times qualify for recovery, processing, distribution, and ultimately for use in a wide variety of surgical procedures where human bone, tissue, etcetera, can be appropriately and safely utilized.

15. Upon information and belief, Donor Services harvested, recovered, processed, supplied, and/or sold human tissue for use in FiberCel which was implanted into Plaintiff, and which is the subject of this complaint.

16. Defendants, at all times relevant to this lawsuit, manufactured, developed, designed, marketed, distributed, promoted, supplied, provided human tissue for, and/or otherwise sold (directly or indirectly) FiberCel to various locations for use in surgeries requiring bone grafting, including to Vidant Medical Center in Greenville, North Carolina, where tuberculosis-contaminated FiberCel was

surgically implanted into Plaintiff Lisa Harris, causing her to suffer harm as described herein.

III. JURISDICTION AND VENUE

17. This Court has jurisdiction over the parties as they have all had substantial contacts with the State of North Carolina and otherwise meet the criteria for personal jurisdiction.

18. The Court has jurisdiction over the subject matter, in that these are state law claims and the amount in controversy exceeds the sum of $75,000, exclusive of interest and costs, and there is diversity of citizenship/removal jurisdiction.

19. At all times relevant to this action, the Defendants have been engaged, either directly or indirectly, in the business of manufacturing, marketing, selling, promoting, and/or distributing FiberCel and/or the human tissue used in FiberCel to various locations for use in surgeries requiring bone grafting within the State of North Carolina, with a reasonable expectation that the product would be used or consumed in this state, and have regularly solicited or transacted business in this State, thereby subjecting the Defendants to personal jurisdiction.

20. Venue is proper in this Court.

IV. FACTUAL ALLEGATIONS

A. FiberCel Fiber Viable Bone Matrix

21. The FiberCel Fiber Viable Bone Matrix product is made from processed human tissue consisting of cancellous bone particles with preserved living cells, combined with demineralized cortical fiber. FiberCel is used as a bone void filler in various orthopedic and spinal procedures. The allografts contain the scaffold, growth factors, and cells required for regeneration critical for successful bone formation.

22. FiberCel is classified by the FDA as a human cell, tissue, cellular or tissue-based product (HCT/P). HCT/Ps are regulated by the FDA as drugs, devices, and/or other biological products.

23. FiberCel is marketed for use in orthopedic and reconstructive bone grafting procedures with the use of autologous bone or other forms of allograft bone or alone as a bone graft.

24. The FiberCel package insert states that "THIS PRODUCT IS MANUFACTURED FROM DONATED HUMAN TISSUE," which consists of highly processed donor tissue and growth factor cells. The exact formulation of FiberCel is closely held by Defendants and is not known to Plaintiffs.

25. Because FiberCel uses human tissue from human donors and includes preserved living cells, it is imperative that rigorous screening and quality control procedures be used to ensure that the resultant product is not contaminated. This is also so because the FiberCel product is meant to be used in surgeries and medical

procedures involving patients already in a vulnerable medical status given their context as procedure recipients.

26. On June 20, 2019, Aziyo announced it had signed an exclusive, multiyear distribution agreement with Medtronic/Spinalgraft in the U.S. orthopedic market. According to the agreement, Aziyo agreed to manufacture and supply FiberCel to Medtronic/Spinalgraft for distribution through the Medtronic/Spinalgraft sales and marketing organization.

27. Medtronic/Spinalgraft, along with their affiliates, comprise a very large and sophisticated medical manufacturer and distributor. The enterprise holds itself out as having special knowledge and expertise regarding the medical products that it carries and distributes, and in fact even has training and instructional videos pertaining to the use of the FiberCel product on its Medtronic English language website.

28. Upon information and belief, in addition to distributing FiberCel, Medtronic/Spinalgraft developed FiberCel along with Defendant Aziyo Biologics, Inc.

29. The FiberCel used in Plaintiff's surgery was manufactured using contaminated human tissue recovered from a single donor by DCI Donor Services, Inc. and New Mexico Donor Services ("Donor Services").

30. Upon information and belief, the single donor whose tissue was recovered by Donor Services had a tuberculosis infection prior to his death and had clear signs and symptoms at the time of his death of an infectious etiology.

B. The FiberCel Product is Recalled.

31. On June 2, 2021, the United States Food & Drug Administration ("FDA") issued an urgent voluntary recall of FiberCel, specifically three products from Donor Lot Number NMDS210011: VMB9901, VBM9905, and VBM9910.

32. Aziyo initiated the voluntary recall in response to reports of patients testing positive for Tuberculosis and post-surgical infections following the surgical implantation of FiberCel as part of an orthopedic or spinal procedure.

33. Tuberculosis ("TB") is an infectious disease caused by bacteria known as *Mycobacterium tuberculosis*. TB is highly contagious and mostly impacts the lungs, but can also spread through the lymph nodes to other parts of the body including the kidneys, brain, and spine.

34. Once Mycobacterium tuberculosis is introduced to the body, the bacteria must then proliferate within the new host for the host to develop disease. When this bacterium is introduced in a surgical wound, the patient is already in an immunocompromised position, causing them to have an increased likelihood of developing TB, which can be fatal.

35. The recalled contaminated FiberCel units were delivered to at least 20 states, including North Carolina.

36. Dozens of patients that have received FiberCel from this Donor Lot have tested positive for TB, including Plaintiff.

37. In a press release dated June 7, 2021, Aziyo acknowledged:

> [L]earning of post-surgical infections in patients treated with FiberCel, including some patients that tested positive for tuberculosis. The lot consists of 154 units of FiberCel, all derived from a single donor, that were shipped to facilities in 20 states. Aziyo is investigating the source of the infections in coordination with its distributor, the U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention. The Company is in the process of recovering the unused units from this lot….

38. The product recall acknowledged that viruses and bacteria, including TB, can be transplanted into patients along with the FiberCel product.

C. Plaintiff Received the Contaminated FiberCel Product and Suffered Severe Injury.

39. Plaintiff Lisa Harris underwent spinal surgery on March 17, 2021, at Vidant Medical Center in Greenville, North Carolina.

40. The surgery was performed by Dr. Jennifer Griswold, M.D., a neurosurgeon certified by the American Board of Neurological Surgery, at Vidant Medical Center in Greenville.

41. During Plaintiff's surgery, Dr. Griswold implanted the FiberCel product, Lot Number NMDS210011, into Plaintiff's body.

42. The FiberCel product contained no adequate warning to Dr. Griswold or to Plaintiff of the danger that she could contract TB if a FiberCel product was used during the surgery.

43. Unbeknownst to Plaintiff or her physicians at the time of her surgery, the FiberCel implanted into Plaintiff was contaminated with TB.

44. While the surgery was initially a success, Plaintiff soon began experiencing problems.

45. On June 7, 2021, Plaintiff's physicians notified Plaintiff she may have been exposed to TB from the FiberCel that was implanted during her surgery. Plaintiff subsequently tested positive for TB.

46. Plaintiff's TB was caused by the contaminated and recalled FiberCel used in her operation, which contained contaminated human tissue recovered by Donor Services and developed, manufactured, sold, and distributed by the Aziyo and Medtronic defendants.

47. As a direct and proximate result of the implantation of contaminated FiberCel, Plaintiff was and is forced to undergo a grueling medical protocol to manage her TB diagnosis and has had to undergo additional surgeries as a result of the TB infection.

48. Plaintiff will require continued medical monitoring now and into the future in order to monitor Plaintiff's health related to the ongoing and serious nature of her TB diagnosis.

49. Plaintiff would not have suffered from TB had Defendants sold and distributed a product and recovered human tissue that was free from TB contamination.

50. Plaintiff further has experienced significant side effects from the extensive treatments causing a cascade of sequential complications caused by the contaminated FiberCel product.

51. As a direct and proximate result of Plaintiff's exposure to Defendants' contaminated FiberCel product and human tissue recovered for use in FiberCel, which was used in her spinal surgery, Plaintiff has suffered and continues to suffer from pain and discomfort, severe emotional distress, the loss of daily functions, and economic loss, including, but not limited to, present and future medical expenses, lost earnings, and future lost earning capacity, all as a direct result of Defendants' liability producing conduct.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION
NEGLIGENCE
(Against Elutia Inc. f/k/a Aziyo Biologics, Inc., Medtronic Sofamor Danek USA, Inc., and Spinalgraft Technologies LLC

52. Plaintiffs incorporate the foregoing paragraphs 1 through 51 as though the same were set forth at length herein.

53. Defendants Aziyo and Medtronic/Spinalgraft owed a duty to Plaintiff Lisa Harris to exercise reasonable care in designing, developing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and distribution of FiberCel into the stream of commerce, including a duty to assure that the FiberCel would not cause those who used it, including Plaintiff, to suffer adverse harmful effects.

54. Defendants Aziyo and Medtronic/Spinalgraft failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and distribution of FiberCel.

55. Defendants Aziyo and Medtronic/Spinalgraft knew or should have known that those individuals who used the defective FiberCel were at risk for suffering harmful effects from it, including but not limited to, TB, as well as other severe injuries which are permanent and lasting in nature, physical pain, mental anguish, and diminished enjoyment of life.

56. Defendants Aziyo and Medtronic/Spinalgraft were negligent in designing, developing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing, and sale of

FiberCel. The negligence of Defendants Aziyo and Medtronic/Spinalgraft, their agents, servants, and employees, included, but was not limited to, the following acts and/or omissions:

a. Designing, developing, manufacturing, producing, creating, and/or promoting FiberCel without adequately, sufficiently, or thoroughly testing the FiberCel units to ensure they were free from contamination of communicable diseases, including but not limited to, TB;

b. Negligently selling their FiberCel product which was contaminated with TB;

c. Not conducting a sufficient quality control testing program to determine whether or not the subject FiberCel was manufactured properly and was free from contamination or other defects making it unsafe for users of the product;

d. Failing to have a sufficient quality control program to ensure that the donor whose tissue was used in the subject FiberCel was free from communicable disease;

e. Failing to adequately and properly obtain and review complete donor medical history of the donor whose tissue was used in the product;

f. Failing to adequately and properly review the entire donor chart for signs and symptoms of communicable disease;

g. Failing to recognize signs and symptoms of communicable disease in the donor whose tissue was used in the recalled FiberCel;

h. Negligently making a donor eligibility determination;

i. Failing to follow applicable statutes, regulations, FDA guidelines, AATB rules, and industry standards in determining that donor tissue used in the recalled FiberCel was eligible for use in the product;

j. Negligently failing to timely recall their dangerous and defective FiberCel lots at the earliest date that it became known that certain lots of FiberCel were, in fact, dangerous and defective;

k. Negligently manufacturing FiberCel in a manner that was dangerous to those individuals who had FiberCel implanted into their bodies;

l. Negligently producing FiberCel in a manner that was dangerous to those individuals who had it transplanted into their bodies;

m. Negligently and carelessly using human tissue from an unqualified and inadequately screened human donor;

n. Were grossly negligent by willfully ignoring factors that should have led the donor to be deemed ineligible for tissue recovery;

o. Failing to warn individuals who were using the product of the risks of contracting tuberculosis;

p. Acting otherwise careless and negligently; and

q. Were otherwise negligent as shall be shown through discovery and at trial.

57. Defendants Aziyo and Medtronic/Spinalgraft knew or should have known that consumers such as Plaintiff would suffer foreseeable injury and be at increased risk of suffering an injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

58. Defendant Aziyo's and Medtronic/Spinalgraft's negligence was the proximate cause of and was a substantial factor in causing Plaintiff's physical, mental, emotional injuries and harm, and economic loss.

59. Pursuant to N.C.G.S. § 99B-5, each of the Defendant manufacturers and sellers herein acted unreasonably in failing to provide such warning or instruction, and their failure to provide adequate warning or instruction was a proximate cause of the harm for which damages are sought.

60. At the time the product left the control of the manufacturer or seller, the product, without an adequate warning or instruction, created an unreasonably dangerous condition that the manufacturer or seller knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm to a reasonably foreseeable claimant.

61. After the product left the control of the manufacturer or seller, the Defendants as manufacturers or sellers became aware of, or in the exercise of ordinary care should have known, that the product posed a substantial risk of harm to a reasonably foreseeable user or consumer. However, Defendants Aziyo and Medtronic/Spinalgraft failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.

62. By reason of the foregoing, Defendants Aziyo and Medtronic/Spinalgraft are liable to Plaintiff for all of her injuries, harm, damages, and economic and non-economic losses in an amount to be determined in the future in excess of $75,000.

SECOND CAUSE OF ACTION
NEGLIGENCE
(Against DCI Donor Services, Inc. and New Mexico Donor Services)

63. Plaintiffs incorporate paragraphs 1 through 62 as though the same were set forth at length herein.

64. Defendants Donor Services owed a duty to Plaintiff to exercise reasonable care in harvesting, recovering, processing, supplying, promoting, selling, testing, quality assurance, quality control, and distribution of human tissue into the stream of commerce, including a duty to assure that their human tissue, which was used in the subject FiberCel lot, would not cause those who used it, including Plaintiff, to suffer adverse harmful effects.

65. Defendants Donor Services failed to exercise reasonable care in the harvesting, recovering, processing, supplying, testing, quality assurance, quality control, sale, and distribution of their human tissue for use in FiberCel.

66. Defendants Donor Services knew or should have known that those individuals who were exposed to their contaminated human tissue used in FiberCel were at risk for suffering harmful effects from it, including but not limited to, tuberculosis, as well as other severe injuries which are permanent and lasting in nature, physical pain, mental anguish, and diminished enjoyment of life.

67. Defendants Donor Services was negligent in the harvesting, recovering, processing, supplying, testing, quality assurance, quality control, sale, and

distribution of their human tissue for use in FiberCel. The negligence of Defendants Donor Services, their agents, servants, and employees, included, but was not limited to, the following acts and/or omissions:

a. Harvesting, recovering, processing, and selling human tissue for use in FiberCel without adequately, sufficiently, or thoroughly testing the human tissue to ensure that it was free from contamination of communicable diseases, including but not limited to, TB;

b. Not conducting a sufficient quality control testing program to determine whether or not the subject human tissue used in the aforementioned defective FiberCel lot was properly recovered and was free from contamination or other defects making it unsafe;

c. Failing to adequately and properly obtain and review complete donor medical history;

d. Failing to stop the tissue recovery process once signs and symptoms of infection were discovered;

e. Failing to have medical professionals review the subject donor's body, medical records, and donor chart;

f. Negligently failing to timely recall their dangerous and contaminated human tissue at the earliest date that it became known that its human tissue sold for use in FiberCel was in fact, dangerous and defective;

g. Negligently harvesting, recovering, and selling human tissue for use in FiberCel in a manner that was dangerous to those individuals who had FiberCel implanted into their bodies;

h. Negligently and carelessly recovering tissue from an unqualified and inadequately screened human donor;

i. Negligently failing to screen the human donor whose tissue was used in the subject lot of FiberCel for signs of infection or disease that would have led Defendants to stop the tissue recovery process;

j. Negligently failing to test the human donor tissue and/or bone;

k. Failing to warn individuals who were using their human tissue of the risks of contracting TB;

l. Were grossly negligent by willfully ignoring factors that should have led the donor to be deemed ineligible for tissue recovery;

m. Acting in bad faith by failing to recognize obvious signs and symptoms of communicable disease of the donor and instead selling contaminated human tissue from the donor to be used in products that would be implanted into living individuals; and

n. Acting otherwise careless and negligently as shall be shown through discovery and at trial.

68. Defendants Donor Services knew or should have known that consumers, such as Plaintiff, would suffer foreseeable injury and be at increased risk of suffering an injury as a result of Donor Services' failure to exercise ordinary care, as set forth above.

69. Defendants Donor Services' negligence was the proximate cause of and was a substantial factor in causing Plaintiff's physical, mental, emotional injuries and harm, and economic loss.

70. Pursuant to N.C.G.S. § 99B-5, each of the Defendant manufacturers and sellers herein acted unreasonably in failing to provide such warning or instruction, and their failure to provide adequate warning or instruction was a proximate cause of the harm for which damages are sought.

71. At the time the human tissue left the control of the manufacturer or seller, without an adequate warning or instruction, created an unreasonably dangerous condition that the manufacturer or seller knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm to a reasonably foreseeable claimant.

72. After the human tissue left the control of the manufacturer or seller, the Defendants as manufacturers or sellers became aware of, or in the exercise of ordinary care should have known, that the human tissue posed a substantial risk of harm to a reasonably foreseeable user or consumer. However, Defendants Donor Services failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.

73. By reason of the foregoing, Defendants Donor Services are liable to Plaintiff for all her injuries, harm, damages, and economic and non-economic losses in an amount to be determined in the future in excess of $75,000.

THIRD CAUSE OF ACTION
DEFECTIVE DESIGN AND MANUFACTURE
(Against Elutia Inc. f/k/a Aziyo Biologics, Inc., Medtronic Sofamor Danek USA, Inc., and Spinalgraft Technologies LLC LLC)

74. Plaintiffs incorporate the foregoing paragraphs 1 through 73 as though the same were set forth at length herein.

75. At all times material to this lawsuit, Defendants Aziyo and Medtronic/Spinalgraft were engaged in the business of designing, manufacturing, testing, marketing, distributing, and/or selling FiberCel for the sale to, and use by, members of the public.

76. Defendants Aziyo and Medtronic/Spinalgraft manufactured, distributed, and/or sold the FiberCel product which was implanted into Plaintiff's body during her spinal surgery.

77. The FiberCel manufactured by Defendants Aziyo and Medtronic/Spinalgraft reached Plaintiff without substantial change in its condition when it was implanted into her spine during her operation.

78. The FiberCel was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Plaintiff.

79. Pursuant to N.C.G.S. § 99B-6, at the time of its manufacture, the manufacturer acted unreasonably in designing or formulating the product, that this conduct was a proximate cause of the harm for which damages are sought, and at the time the product left the control of the manufacturer, the manufacturer unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design or formulation that could then have been reasonably adopted and that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product.

80. At the time the product left the control of the manufacturer, the design or formulation of the product was so unreasonable that a reasonable person, aware of the relevant facts, would not use or consume a product of this design.

81. Under the circumstances Defendant Aziyo's and Medtronic/Spinalgraft's conduct was negligent with regard to the design of the product in that Defendant Aziyo's and Medtronic/Spinalgraft's lack of adequate quality control systems allowed the product to reach the injured claimant as occurred; and in considering:

a. The nature and magnitude of the risks of harm associated with the design or formulation in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product;

b. The likely awareness of product users, whether based on warnings, general knowledge, or otherwise, of those risks of harm;

c. The extent to which the design or formulation conformed to any applicable government standard that was in effect when the product left the control of its manufacturer;

d. The utility of the product, including the performance, safety, and other advantages associated with that design or formulation;

e. The technical, economic, and practical feasibility of using an alternative design or formulation at the time of manufacture;

f. The nature and magnitude of any foreseeable risks associated with the alternative design or formulation; and

g. Acting otherwise careless and negligently as shall be shown through discovery and at trial.

82. Defendants Aziyo and Medtronic/Spinalgraft owe a duty to the general public, specifically to Plaintiff, to exercise reasonable care in the design, study, development, manufacture, promotion, sale, marketing, and distribution of FiberCel. Defendants Aziyo and Medtronic/Spinalgraft failed to exercise reasonable care in the design of FiberCel because, as designed, FiberCel was capable of causing serious personal injuries such as those suffered by Plaintiff during the foreseeable use of FiberCel.

83. The FiberCel implanted into Plaintiff was defective and, because of its defects, was unreasonably dangerous to persons who might reasonably be expected to require its use. In addition, this product was dangerous to the extent beyond that which could reasonably be contemplated by Plaintiff.

84. The FiberCel implanted into Plaintiff was defective at the time it was distributed by Defendants Aziyo and Medtronic/Spinalgraft or left their control.

85. Plaintiff was a person who would reasonably be expected to use FiberCel.

86. Defendant Aziyo's and Medtronic/Spinalgraft's failure to exercise reasonable care in the design, marketing, selling, distributing, and manufacturing of FiberCel was a proximate cause of Plaintiff's injuries and damages.

87. As a direct and proximate result of the actions and inactions of the Defendants Aziyo and Medtronic/Spinalgraft as set forth above, Plaintiff was

exposed to FiberCel, and suffered the injuries and damages set forth hereinabove and was damaged in an amount in excess of $75,000.

FOURTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY
(Against Elutia Inc. f/k/a Aziyo Biologics, Inc., Medtronic Sofamor Danek USA, Inc., and Spinalgraft Technologies LLC LLC)

88. Plaintiffs incorporate the foregoing paragraphs 1 through 87 as though the same were set forth at length herein.

89. Defendants Aziyo and Medtronic/Spinalgraft are in the business of designing, manufacturing, supplying, selling, and placing into the stream of commerce certain goods, including FiberCel. By placing FiberCel into the stream of commerce, Defendants Aziyo and Medtronic/Spinalgraft impliedly warranted that it was merchantable and fit and safe for its intended use.

90. A warranty that the goods were merchantable was implied in all relevant contracts for the sale of the instant product, and furthermore, any Defendant sellers were merchants with respect to goods of that kind. N.C.G.S. § 25-2-314.

91. The FiberCel manufactured and/or sold and was placed into the stream of commerce by Defendants Aziyo and Medtronic/Spinalgraft and implanted into Plaintiff was contaminated, leading persons who received FiberCel implants to develop tuberculosis, including Plaintiff, and accordingly, was not fit, safe, or merchantable for its intended use.

92. The contamination in the FiberCel, manufactured, supplied, and placed into the stream of commerce by Defendants Aziyo and Medtronic/Spinalgraft, was present at the time the FiberCel units left Defendants' control and at the time it was implanted into Plaintiff as part of her spinal operation.

93. Defendants Aziyo and Medtronic/Spinalgraft breached the implied warranty for FiberCel because it was contaminated, unmerchantable, and not fit for its intended purpose, resulting in personal injuries suffered by Plaintiff, including her development of tuberculosis.

94. Plaintiff was a foreseeable user of the FiberCel designed, manufactured, and placed into the stream of commerce by Defendants Aziyo and Medtronic/Spinalgraft.

95. By reason of the foregoing, Defendants Aziyo and Medtronic/Spinalgraft are liable to Plaintiff for her injuries, harm, damages, and economic and non-economic losses in an amount in excess of $75,000 to be determined at trial.

FIFTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
(Against Elutia Inc. f/k/a Aziyo Biologics, Inc., Medtronic Sofamor Danek USA, Inc., and Spinalgraft Technologies LLC LLC)

96. Plaintiffs incorporate the foregoing paragraphs 1 through 95 as though the same were set forth at length herein.

97. At all times mentioned, Defendants Aziyo and Medtronic/Spinalgraft expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants Aziyo and Medtronic/Spinalgraft and their authorized agents or sales representatives, orally and in publications, package inserts, and other written materials intended for physicians, medical patients, and the public, that FiberCel is safe, effective, fit, and proper for its intended use. Plaintiff and Plaintiff's physicians utilized FiberCel relying upon these warranties.

98. Defendant Aziyo's and Medtronic/Spinalgraft's own promotional materials and information state that FiberCel is processed in sterile conditions and is screened for bacteria and communicable disease.

99. In utilizing FiberCel, Plaintiff relied on the skill, judgment, representation, and foregoing express warranties of Defendants Aziyo and Medtronic/Spinalgraft. These warranties and representations were false in that FiberCel is unsafe and unfit for its intended uses.

100. As a result of the abovementioned breach of express warranties by Defendants Aziyo and Medtronic/Spinalgraft, Plaintiff suffered injuries and damages as alleged herein in excess of $75,000.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
(Against DCI Donor Services, Inc. and New Mexico Donor Services)

101. Plaintiffs incorporate the foregoing paragraphs 1 through 100 as though the same were set forth at length herein.

102. At all times mentioned, Defendants Donor Services expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants Donor Services and their authorized agents or sales representatives, orally and in publications, package inserts, websites, and other written materials intended for physicians, medical patients, and the public, that their human tissue sold for use in FiberCel is safe, effective, fit, and proper for its intended use. Plaintiff and Plaintiff's physicians utilized FiberCel and the human tissue used in FiberCel relying upon these warranties.

103. In utilizing FiberCel and the human tissue used in FiberCel, Plaintiff relied on the skill, judgment, representation, and foregoing express warranties of Defendants Donor Services. These warranties and representations were false in that FiberCel and its human tissue component are unsafe and unfit for its intended uses.

104. As a result of the abovementioned breach of express warranties by Defendants Donor Services, Plaintiff suffered injuries and damages as alleged herein in excess of $75,000.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY
(Against DCI Donor Services, Inc. and New Mexico Donor Services)

105. Plaintiffs incorporate the foregoing paragraphs 1 through 104 as though the same were set forth at length herein.

106. Defendants Donor Services is in the business of harvesting, recovering, selling, and placing into the stream of commerce certain goods and/or services, including the sale of human tissue. By placing human tissue into the stream of commerce to be used in surgical procedures, including the Plaintiff's surgical procedure in March 2021, Defendants Donor Services impliedly warranted that it was merchantable and fit and safe for its intended use.

107. A warranty that the goods and/or services were merchantable was implied in all relevant contracts for the sale of the instant product, and furthermore, any Defendant sellers were merchants with respect to goods of that kind. N.C.G.S. § 25-2-314.

108. The tuberculosis-contaminated human tissue sold by Defendants Donor Services and placed into the stream of commerce by Defendants Donor Services and implanted into Plaintiff was contaminated, leading persons who received FiberCel utilizing contaminated human tissue sold by Donor Services to develop tuberculosis, including Plaintiff, and accordingly, was not fit, safe, or merchantable for its intended use.

109. The contamination in the human tissue, harvested, recovered, supplied, sold, and placed into the stream of commerce by Defendants Donor Services was

present at the time the human tissue left Defendants' control and at the time it was implanted into Plaintiff as part of her spinal operation.

110. Defendants Donor Services breached the implied warranty for its human tissue because it was contaminated, unmerchantable, and not fit for its intended purpose, resulting in personal injuries suffered by Plaintiff, including her development of TB.

111. Established medical and technological procedures existed at the time Defendants Donor Services harvested, recovered, supplied, and sold the tuberculosis-contaminated human tissue that could have been employed pursuant to the standards of local medical practice that would have detected the presence of an infection in the donor, including but not limited to, the detection of TB.

112. Had established medical and technological procedures been employed, including but not limited to additional blood testing, Defendants Donor Services could have discovered that its tissue was contaminated with TB and could have prevented its human tissue from being disseminated for use in surgical procedures.

113. Plaintiff was a foreseeable user and/or recipient of the human tissue harvested, recovered, supplied, sold, and placed into the stream of commerce by Defendants Donor Services.

114. By reason of the foregoing, Defendants Donor Services are liable to Plaintiff for her injuries, harm, damages, and economic and non-economic losses in an amount in excess of $75,000 to be determined at trial.

EIGHTH CAUSE OF ACTION
LOSS OF CONSORTIUM
(Against All Defendants)

115. Plaintiffs incorporate the foregoing paragraphs 1 through 114 as though the same were set forth at length herein.

116. During the pertinent time, the negligence of the Defendants proximately caused Plaintiff Oral Duane Harris, Jr. to lose the consortium of his spouse, Plaintiff Lisa Harris.

117. Mr. and Mrs. Harris were legally married at the time of Plaintiff Lisa Harris' above-alleged injury.

118. During the pertinent times, Plaintiff Oral Duane Harris, Jr.'s marital relationship with his spouse had beneficial aspects including but not limited to marital services, society, affection, and companionship.

119. As a direct and proximate result of Defendants' negligence, for a significant period of time, Plaintiff Oral Duane Harris, Jr. has lost the consortium of his spouse. There has been a disruption of marital services, society, and companionship.

120. Defendants' negligence was a substantial factor in causing the loss of consortium.

121. Accordingly, Defendants should be jointly and severally found liable to the Plaintiff Oral Duane Harris, Jr. in an amount of damages as may be found by a jury at trial herein.

NINTH CAUSE OF ACTION
PUNITIVE DAMAGES
(Against All Defendants)

122. Plaintiffs incorporate the foregoing paragraphs 1 through 121 as though the same were set forth at length herein.

123. Plaintiffs are further informed and believe that Defendants' misconduct, as previously outlined herein, constituted a conscious disregard for the rights and safety of other persons, including Plaintiff, that had a great probability of causing substantial harm including, but not limited to, exposing Plaintiff and other recipients of FiberCel and the human tissue used in FiberCel to TB, a potentially deadly infectious disease.

124. Plaintiffs are further informed and believe that Defendants engaged in conduct with respect to the contaminated FiberCel unit alleged herein which was a legal cause of loss, damages, injuries, and harm to Plaintiff, and which exposed Plaintiff and other recipients of the contaminated FiberCel units to serious complications, including the diagnosis of TB in Plaintiff's post-surgical wound.

125. Defendants' actions and inactions leading to the contamination of the FiberCel product were outrageous, willful and wanton, and done with reckless disregard for the safety of the Plaintiff.

126. Under the circumstances, Defendants' conduct gave rise to an aggravating factor for purposes of the North Carolina punitive damages statute, N.C.G.S. § 1D-1 *et seq*.

127. The Defendants' outrageous, willful and wanton, and reckless conduct in disregard of the safety of the Plaintiff was the direct proximate cause of Plaintiff's injuries and damages.

128. As a direct and proximate result of the Defendants' outrageous, willful and wanton, and reckless conduct in disregard of the safety of the Plaintiff, the Plaintiffs have suffered and continue to suffer damages as set forth above.

129. Defendants thereby acted with a conscious disregard for the rights and safety of Plaintiff and other users of the contaminated FiberCel units, thus warranting an award of punitive damages to Plaintiff.

130. As a result of the willful, wanton or reckless conduct by Defendants giving rise to an aggravating factor under Chapter 1D, and to the extent the evidence may show, Plaintiffs are entitled to an award of punitive damages to punish and deter.

JURY DEMAND

Plaintiffs request a trial by jury of all claims herein so triable.

PRAYER FOR RELIEF

WHEREFORE**,** Plaintiffs pray for relief against Defendants, jointly and severally, as follows:

a. Compensatory damages, exclusive of interest and costs, and in an amount to fully compensate Plaintiffs for all past, present, and future pain, and suffering;

b. Special damages, exclusive of interest and costs, and in an amount to fully compensate Plaintiff Lisa Harris for all of her injuries and damages, both past and present;

c. Punitive and/or exemplary damages for the outrageous, willful and wanton, and reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;

d. An award of damages for loss of consortium to fully compensate Oral Duane Harris, Jr.;

e. To the extent the law may allow same, an award of expenses and costs of this action, as well as any attorney fees that may be applicable;

f. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

g. Such further relief as this Court deems necessary, just, and proper.

Respectfully submitted this the 8th day of March, 2024.

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